Tetramethylammonium halides: Human health tier II assessment

28 June 2019

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Methanaminium, N,N,N-trimethyl-, bromide	64-20-0
Methanaminium, N,N,N-trimethyl-, chloride	75-57-0
Methanaminium, N,N,N-trimethyl-, iodide	75-58-1

Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to

human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit:**www.nicnas.gov.au**

Disclaimer

ACRONYMS & ABBREVIATIONS

Grouping Rationale

The chemicals in this group are tetramethylammonium compounds with the cation being a quaternary ammonium group, with chloride, bromide or iodide counter ions. These chemicals share structural and functional similarities and have similar physicochemical properties and biodegradability. A similar health hazard profile is also expected.

The chemicals in this group have similar reported uses.

The following acronyms and their corresponding CAS numbers will be used in this assessment:

TMAB (CAS No. 64-20-0);

TMAC (CAS No. 75-57-0); and

TMAI (CAS No. 75-58-1).

Import, Manufacture and Use

Australian

The National Pollutant Inventory (NPI) holds data for all sources of the chemicals in Australia.

The following Australian site-limited uses were reported from safety data sheets (SDS) from various Australian companies:

- use as chemical intermediates.

International

The following international uses have been identified through the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers; Galleria Chemica; the Substances and Preparations in Nordic countries (SPIN) database; the European Commission Cosmetic Ingredients and Substances (CosIng) database; the United States (US) Personal Care Products Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary; the Organisation for Economic Cooperation and Development High Production Volume chemical program (OECD HPV); the US Environmental Protection Agency's Aggregated Computer Toxicology Resource (ACToR); the US National Library of Medicine's Hazardous Substances Data Bank (HSDB); and the US Environmental Protection Agency (US EPA) and World Health Organisation INCHEM document (INCHEM, 2003).

The chemical, TMAC has reported cosmetic use as a viscosity controlling agent.

The chemicals have reported commercial uses, including:

- in oil and water based hydraulic fracturing fluids; and
- as ingredients in clay stabilisers.

The chemicals have reported site-limited uses, as:

- chemical intermediates;
- catalysts; and
- inhibitors in chemical synthesis.

Non-industrial uses of the chemicals as therapeutic agents have been reported internationally.

Restrictions

Australian

These chemicals are covered by the group entry for QUATERNARY AMMONIUM COMPOUNDS in Schedules 5 and 6 of the Poisons Standard—the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP, 2019):

Schedule 6:

'QUATERNARY AMMONIUM COMPOUNDS except:

a) when separately specified in these Schedules;

b) when included in Schedule 5;

c) dialkyl or dialkoyl quaternary ammonium compounds where the alkyl or alkoyl groups are derived from tallow or hydrogenated tallow or similar chain length (C16/C18) sources; or

d) in preparations containing 5 per cent or less of such quaternary ammonium compounds.'

Schedule 5:

'QUATERNARY AMMONIUM COMPOUNDS in preparations containing 20 percent or less of quaternary ammonium compounds except:

a) when separately specified in these Schedules;

b) dialkyl or dialkoyl quaternary ammonium compounds where the alkyl or alkoyl groups are derived from tallow or hydrogenated tallow or similar chain length (C16/C18) sources; or

c) in preparations containing 5 per cent or less of such quaternary ammonium compounds.'

Schedule 6 chemicals are described as 'Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label'. Schedule 6 chemicals are labelled with 'Poison' (SUSMP, 2019).

Schedule 5 chemicals are described as 'Substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.' Schedule 5 chemicals are labelled with 'Caution' (SUSMP, 2019).

International

The chemical, TMAC is listed on the following Health Canada List of prohibited and restricted cosmetic ingredients (The Cosmetic Ingredient 'Hotlist') (Galleria Chemica).

Existing Worker Health and Safety Controls

Hazard Classification

The chemical, TMAC is classified as hazardous, with the following hazard categories and hazard statements for human health in the Hazardous Chemical Information System (HCIS) (Safe Work Australia):

Acute Toxicity – Category 3; H301 (Toxic if swallowed)

Acute Toxicity – Category 3; H311 (Toxic in contact with skin)

Skin Irritation – Category 2; H315 (Causes skin irritation).

Exposure Standards

Australian

No specific exposure standards are available fo

r any of the chemicals in this group.

International

The following exposure standards are identified for TMAC and TMAB in the USA (Galleria Chemica):

Temporary Emergency Exposure Limits (TEELs) defined by the US Department of Energy (DOE) for the chemical are reported as:

TEEL-1= 0.15 mg/m^3;

TEEL-2= 1.7 mg/m^3;

TEEL-3= 9.9 mg/m^3.

The following exposure standards are identified for TMAI (Galleria Chemica):

The American Conference of Governmental Industrial Hygienists (ACGIH) recommends a threshold limit value (TLV) of 0.01 ppm time weighted average (TWA) and a short term exposure limit (STEL) of 0.1 ppm.

Health Hazard Information

The toxicity of tetramethylammonium salts, including the chemicals in this assessment, is considered to be due to the presence of the tetramethylammonium cation. The anion components are not considered to contribute to the toxicity of the chemicals.

Only limited data are available for 2 chemicals in this group, (TMAB, CAS No. 64-20-0 and TMAI, CAS No. 75-58-1). Most of the available data are for TMAC (CAS No. 75-57-0). Therefore, unless specifically stated, toxicity study data used in the assessment is for TMAC and should be read-across for all chemicals in this group to represent the toxicity of the tetramethylammonium cation. This report should be read in conjunction with the IMAP Human Health Tier II assessment report for tetramethylammonium hydroxide and its pentahydrate (available at **www.nicnas.gov.au**) (NICNAS).

Toxicokinetics

Although limited data are available for specific chemicals in this group, quaternary ammonium compounds are known to be poorly absorbed via the oral route. Dermal absorption is also very low. However, dermal absorption can occur through damaged skin (IPCS, 1999; REACH).

TMAC is taken up via passive diffusion after oral administration due to its high water solubility and low molecular weight. It readily dissociated into a chloride-ion and a quaternary ammonium ion. Radiolabelled TMAC was found to be passively taken up into erythrocytes after dissolving completely in the fluids of the gastrointestinal (GI) tract. This uptake is mainly influenced by the varying pH of the GI tract. Once absorbed, it is widely distributed in the body and is mostly excreted via urine. Due to its low vapour pressure (<1.3 x 10e-8 Pa), TMAC is unlikely to reach the tracheobronchial region via inhalation of vapour. However, TMAC may cause irritation and damage the epithelial lining of the respiratory tract leading to systemic uptake of the chemical. Dermal absorption is low due to its very hygroscopic nature and log Kow <-1, indicating that it is not sufficiently lipophilic to cross the stratum corneum (REACH).

Acute Toxicity

Oral

The chemicals have high acute toxicity based on results from animal tests following oral exposure. The median lethal dose (LD50) of TMAC in rats is between 47–172 mg/kg bw, warranting hazard classification.

In an acute oral toxicity study conducted according to the OECD Test Guideline (TG) 401, the LD50 in Wistar rats exposed to the TMAC (2 % v/v concentration in water) by gavage at single doses of 30, 36, 43, 52 and 62 mg/kg bw was calculated to be equivalent to 47 mg/kg bw (in males and females) of pure chemical. Observed effects included sedation, clonic convulsions, dacryorrhoea (excessive secretion of tears) and coma (REACH).

In a study based on OECD TG 425, female Wistar rats were given TMAC (10 % concentration in water) by gavage at doses of 17.5, 55 or 175 mg/kg bw. Mortality observed was 0/1 (17.5 mg/kg bw); 1/2 (55 mg/kg bw) and 2/2 (175 mg/kg bw). Observed effects included convulsions, tremors, sagging eyelids, wet nose/mouth area, flaccid muscle tone, prostration, lethargy, spasms, ataxia and closed eyes. Necropsy of 1 treated, surviving animal showed abnormalities in the pancreas, kidneys and ovaries. The LD50 was determined to be 55 mg/kg bw (REACH).

In another acute oral study, female Sprague Dawley (SD) rats were orally administered single doses of TMAC (15 % aqueous solution) at 300, 550 or 2000 mg/kg bw. Mortality was observed in 3/3 females at 2000 mg/kg bw. Clinical signs observed were: abnormal physical signs including prostration, lethargy, few faeces, chromorhinorrhea (discharge of pigmented secretion from the nose) and wetness of the anogenital area. An LD50 of 1146 TMAC (15 % aqueous solution) mg/kg bw, equivalent to 171.9 mg TMAC was calculated (REACH).

Dermal

Based on the available limited information, the chemicals in this group are considered to have moderate to high acute dermal toxicity and warrant hazard classification.

In an acute dermal toxicity study (OECD TG 402) in rabbits, TMAC (10 % concentration in water) was topically applied at doses of 200 or 500 mg/kg bw for 24 hours. Mortality was recorded as 6/10 animals (4 males and 2 females) at 500 mg/kg bw. Observed effects included lethargy, diarrhoea, few faeces, soiling of anogenital area and abnormalities of the thymus and kidneys. The LD50 was determined to be between 200–500 mg/kg bw (REACH).

Inhalation

No data are available for the chemicals.

Corrosion / Irritation

Skin Irritation

The chemical, TMAC (CAS No. 75-57-0) is classified as hazardous with hazard category 'Skin Irritation Category 2' and hazard statement 'Causes skin irritation (H315) in HCIS (Safe Work Australia). The available data for the chemical support this classification and a hazard classification is recommended for other chemicals in this group, unless data for the specific chemical are available to indicate otherwise (refer to the **Recommendation** section).

In an in vitro skin irritation: reconstructed human epidermis test (EPISKIN model) (OECD TG 439), TMAC was applied to the skin tissue at doses between 10.5 and 11.8 mg. Cells were cultured for 42 hours, 15 minutes after exposure. The cell viability was tested by reduction of MTT. Mean cell viability for the chemical was reported to be 28 %. Since the mean relative tissue viability after exposure to the chemical was below 50 %, the chemical was considered to be irritating to the skin (REACH).

In an in vitro transcutaneous electrical resistance test (TER; OCED TG 431), TMAC was tested for skin corrosion at 25 mg in milli-Q-water in human skin cells. After one hour and three minutes exposure, the cells were cultured for 3 hours in the presence of MTT. Cell viability of 98 % and 92 %, respectively was observed. Cell viability above 50 % indicate the test substance is not corrosive (REACH).

In an in vivo skin irritation study (24 hr occlusively) in New Zealand White (NZW) rabbits (n=6), 0.5 mL of TMAC at 50 % in water was applied on shaved skin (occlusively) for 24 hour; the rabbits were observed for 48 hours following treatment. Slight to well-defined erythema (mean score = 0.3/4 in 4/6 treated animals) and slight oedema (mean score = 0/4 in 1/6 treated animals) were observed at 24 and 48 hours post-exposure. Two treated animals died during the observation period with distinct signs of intoxication, excessive salivation and apathy (REACH).

Eye Irritation

Based on the available data for TMAC (CAS No. 75-57-0), the chemicals are not more than slightly irritating to eyes.

In an in vivo eye irritation study (OECD TG 405), male NZW rabbits (n=3) were treated with 49.8 mg of TMAC in 1 eye and observed for 14 days following treatment. Corneal injury with slight dulling of the normal luster of the eyes was observed in 1 animal on day 1. Redness of conjunctivae and chemosis was observed in all treated animals with mean scores of 1.1/3 and 0.3/4, from 24 to 72 hours, respectively. All effects were fully reversible by day 7 (REACH).

Sensitisation

Skin Sensitisation

Although limited information is available on the skin sensitisation potential of these chemicals, based on the available information, the chemicals in this group are not likely to be skin sensitisers.

In a local lymph node assay (LLNA) conducted according to OECD TG 429, TMAC was not found to be sensitising to the skin in CBA mice. The chemical at concentrations of 5, 10 or 25 % (in propylene glycol) was topically administered once a day for 5 days and stimulation indices of 0, 0.5 and 1.1, respectively were reported. The chemical was not considered to have sensitisation potential (REACH).

Repeated Dose Toxicity

Oral

Based on the limited available data, minimal changes in liver weight and minor haematological changes were observed after repeated exposure to TMAC. The information was not sufficient to warrant hazard classification.

In a 90-day study, TMAC was administered orally to Charles River (Crl:WI(Han)) rats (n=10/sex/dose) at 0, 3, 10 or 30 mg/kg bw/day for 90 days. Two treated males at 30 mg/kg bw/day were found deceased during the study. Dose-dependent, clinical signs seen in the surviving treated animals included lethargy, hunched and/or flat posture, piloerection and ptosis. Statistically significant lower body weight gain was seen in high dose males, while high dose females showed statistically significantly increased relative and absolute liver weights and lower thymus weights. Histopathological examination showed hepatocellular hypertrophy in 4 /10 females at 3 and 10 mg/kg bw/day and in 8/10 females at 30 mg/kg bw/day. Thymus atrophy was seen in all treated females at 30 mg/kg bw/day. A no observed adverse effect level (NOAEL) of 10 mg/kg bw/day was determined (REACH).

Dermal

No data are available.

Inhalation

No data are available.

Genotoxicity

Based on the available in vitro genotoxicity study, the chemicals are not considered to be genotoxic.

Negative results were observed in a bacterial reverse mutation test (OECD TG 471) in *Salmonella typhimurium* (*S. typhimurium* strains TA98, TA100, TA 1535 and TA1537) and *Escherichia coli* WP2 uvrA at concentrations up to 5000 µg/plate, with and without metabolic activation (REACH).

In a read-across study (OECD TG 476) in L5178Y mouse lymphoma cells, a structural analogue, tetramethylammonium hydroxide (TMAH; CAS No. 75-59-2) at concentrations up to 1812 µg/mL, with and without metabolic activation gave negative results (REACH).

In a read-across study (OECD TG 473) in Chinese hamster V79 cells, TMAH was negative for induction of chromosomal aberrations at concentrations between 228–910 µg/mL (REACH).

Carcinogenicity

No data are available.

Reproductive and Developmental Toxicity

Based on the data available for an analogue chemical, tetramethylammonium hydroxide (TMAH; CAS. No. 75-59-2), the chemicals in this group are not expected to cause any reproductive or developmental toxicity.

In a reproductive/developmental toxicity screening test conducted in accordance with OECD TG 421, SD rats (10/sex/dose) were dosed with TMAH at 0, 1, 5 or 20 mg/kg bw/day by gavage. Males were dosed from 14 days prior to mating (32 days including mating) and females were dosed from 14 days prior to mating through gestation and weaning (40–57 days). Decrease in food consumption and locomotor activity were observed in parental animals. No treatment-related effects on reproductive or developmental parameters up to 20 mg/kg bw/day were observed. The NOAEL for reproductive and developmental toxicity was 20 mg/kg bw/day (highest dose tested)(REACH).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include systemic acute toxicity from oral and dermal exposure and local effects (skin irritation).

Public Risk Characterisation

Although the use of chemicals in this group in cosmetic and domestic products in Australia is not known, the chemicals are reported to be used in cosmetic products overseas (see Import, manufacture and use section).

Considering the range of cosmetic and personal care products that may contain the chemicals, the main route of public exposure is expected to be through the skin, and potential oral exposure from lip and oral hygiene products.

The chemicals are currently listed on Schedule 5 and 6 of the SUSMP for 'QUATERNARY AMMONIUM COMPOUNDS'. At concentrations greater than 5 %, a number of warning statements, first aid instructions and safety directions apply.

Currently, there are no restrictions in Australia on using these chemicals in concentrations below 5 %, including in cosmetics or domestic products. However, cosmetic/domestic products containing the chemicals at low concentrations (<5 %) is not considered to pose an unreasonable risk to public health.

Provided that normal precautions are taken to avoid prolonged skin contact and with available controls for quaternary ammonium compounds, the risk to public health posed by cosmetic/domestic products containing the chemicals at low concentrations (<5 %) is not considered to pose an unreasonable risk to public health.

Occupational Risk Characterisation

During product formulation, oral and dermal exposure may occur, particularly where manual or open processes are used. These could include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment. Worker exposure to the chemicals at lower concentrations could also occur while using formulated products containing the chemicals. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical systemic acute and local health effects, the chemicals could pose an unreasonable risk to workers unless adequate control measures to minimise oral and dermal exposure are implemented. The chemicals should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU) at a workplace (such as an employer) has adequate information to determine the appropriate controls.

The data available support an amendment to the hazard classification in the HCIS (Safe Work Australia) (refer to **Recommendation** section).

NICNAS Recommendation

Assessment of these chemicals is considered to be sufficient, provided that the recommended amendment to the classification is adopted, and labelling and all other requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Regulatory Control

Public Health

Products containing the chemicals should be labelled in accordance with state and territory legislation (SUSMP, 2019).

Work Health and Safety

The chemicals are recommended for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below. This does not consider classification of physical hazards and environmental hazards. There are existing classifications for TMAC (CAS No. 75-57-0). In the absence of higher quality skin irritation data, these classifications should also be applied to all members of this group.

From 1 January 2017, under the model Work Health and Safety Regulations, chemicals are no longer to be classified under the Approved Criteria for Classifying Hazardous Substances system.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Not Applicable	Toxic if swallowed - Cat. 3 (H301) Toxic in contact with skin - Cat. 3 (H311)
Irritation / Corrosivity	Not Applicable	Causes skin irritation - Cat. 2 (H315)

[a] Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

[b] Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third Edition.

[*] Existing Hazard Classification. No change recommended to this classification

Advice for industry

Control measures

Control measures to minimise the risk from oral and dermal exposure to the chemicals should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate, or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemicals are used. Examples of control measures that could minimise the risk include, but are not limited to:

- minimising manual processes and work tasks through automating processes;

- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemicals.

Guidance on managing risks from hazardous chemicals are provided in the *Managing risks of hazardous chemicals in the workplace—Code of practice* available on the Safe Work Australia website.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Obligations under workplace health and safety legislation

Information in this report should be taken into account to help meet obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((M)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of the chemicals are prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (M)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of safety data sheets for hazardous chemicals—Code of practice* and *Labelling of workplace hazardous chemicals—Code of practice*, respectively. These codes of practice are available from the Safe Work Australia website.

A review of the physical hazards of these chemicals has not been undertaken as part of this assessment.

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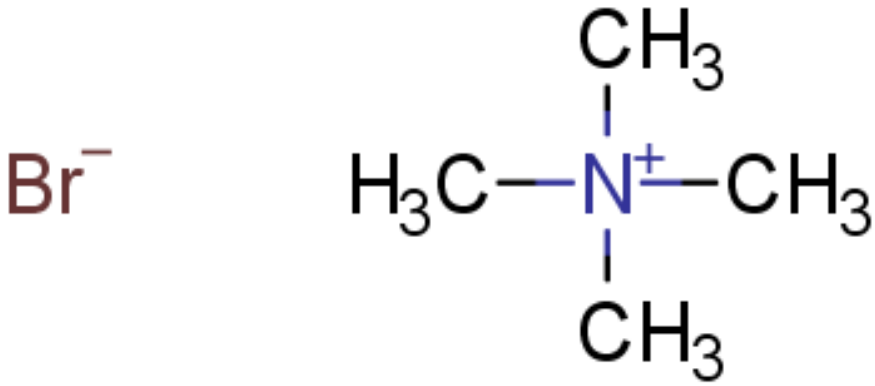
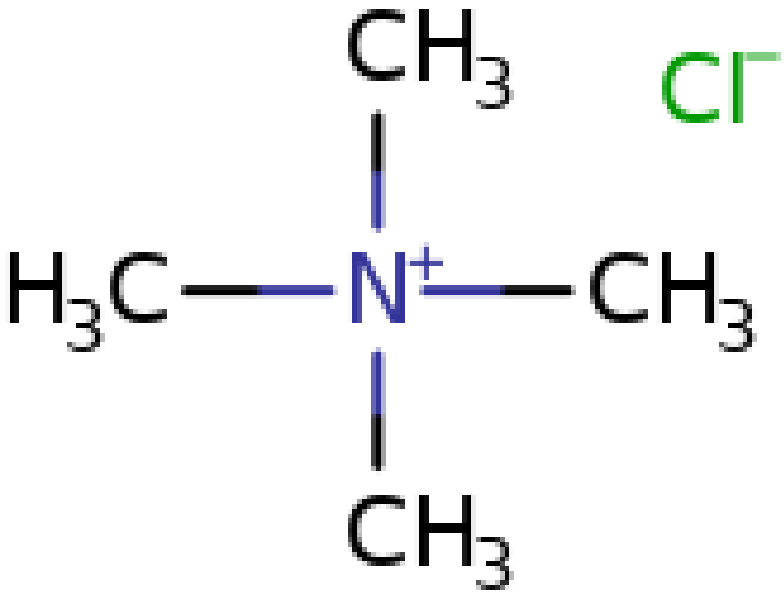
Last Update 28 June 2019

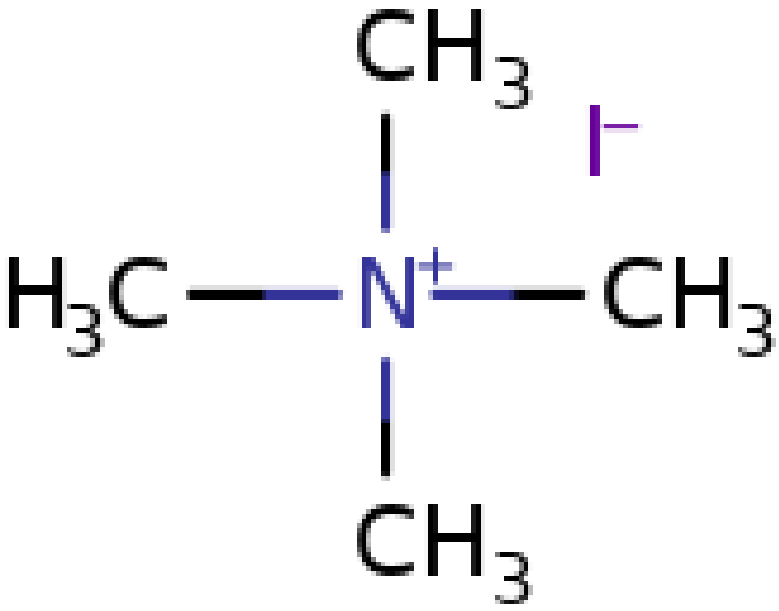
Chemical Identities

Chemical Name in the Inventory and Synonyms	**Methanaminium, N,N,N-trimethyl-, bromide** tetramethylammonium bromide (TMAB)
CAS Number	64-20-0
Structural Formula	
Molecular Formula	C4H12N.Br
Molecular Weight	154.0

Chemical Name in the Inventory and Synonyms	**Methanaminium, N,N,N-trimethyl-, chloride** tetramethylammonium chloride (TMAC) ammmonium, tetramethyl-, chloride
CAS Number	75-57-0

Structural Formula	
Molecular Formula	C4H12N.Cl
Molecular Weight	109.5

Chemical Name in the Inventory and Synonyms	**Methanaminium, N,N,N-trimethyl-, iodide** tetramethylammonium iodide (TMAI)
CAS Number	75-58-1
Structural Formula	

	
Molecular Formula	C4H12N.I
Molecular Weight	201.0

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